UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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In re: ZYPREXA PRODUCTS LIABILITY LITIGATION
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DAVID DIXON *in*:

JAMES CUNNINGHAM, et al.

Plaintiffs,

-against-

ELI LILLY & COMPANY,

Defendant.
----------x

MEMORANDUM, ORDER & JUDGMENT

04-MD-1596

09-CV-1012

JACK B.WEINSTEIN, Senior United States District Judge:

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I. Introduction

Defendant Eli Lilly & Company ("Lilly") moves for summary judgment against plaintiff David Dixon. Plaintiff commenced this action against Lilly in the United States District Court for the Eastern District of New York on March 6, 2009.

The action is essentially a negligence claim, based on a failure to warn. It seeks money damages for injuries, alleging that: (1) Zyprexa, a drug produced by Lilly, caused plaintiff's diabetes and pancreatitis; (2) Lilly failed to warn of the dangers of Zyprexa; and (3) Zyprexa would not have been prescribed, and diabetes or pancreatitis would not have been suffered, if proper warnings had been given.

Argument on Lilly's summary judgment motion was heard on March 31, 2010. Plaintiff requested, and was granted, 45 days to conduct additional discovery concerning issues raised in the motion. The 45 days having elapsed, plaintiff has made no additional submission to the court, and has initiated no further discovery. *See* May 18, 2010 letter from Lilly's counsel, Docket Entry No. 16.

For the reasons below, plaintiff's claims are barred by New York's statute of limitations. The Court of Appeals for the Second Circuit recently raised some doubts regarding the operation of New York's limitations period, and certified three questions to the New York Court of Appeals. *See Giordano v. Market America, Inc.*, 599 F.3d 87, 101 (2d Cir. 2010). (certifying

questions regarding N.Y. C.P.L.R. § 214-c(4)). The certified questions have been accepted by the New York Court, to be decided after briefing and argument. *Giordano v. Market America, Inc.*, -- N.E.2d ----, 2010 WL 1704515 (N.Y. Apr. 29, 2010). While those certified questions are pending, the law remains unchanged. Based on the law as it now stands, defendant's motion must be granted based on the statute of limitations.

The pending motion is decided now without waiting for answers, if any, to the certified questions. This court does not have the luxury of the appellate court in seeking guidance from the New York court—it must decide the matter before it. Decision now will permit the case to wend its way on appeal without loss of time while the appellate courts decide the future law.

II. Facts

The present case is part of a massive and highly complex multidistrict litigation that has included claims by individual Zyprexa users, state attorneys general, third-party payors, and other entities alleging physical or financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with Zyprexa. Like the present plaintiff, they principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending physicians been aware of the risks, they would not have taken Zyprexa. The court has previously detailed the procedural history and factual background of this multidistrict litigation. *See, e.g., Mississippi v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 671 F. Supp. 2d 397 (E.D.N.Y. 2009); *Blume v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 3596982 (E.D.N.Y. Oct. 20, 2009).

A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine, one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. FDA Labeling and "Dear Doctor Letter"

The original 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

> Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses ≥ 2.5 mg/day) where the incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.
>
> The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert 11 (Oct. 1, 1996) (original emphasis).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight-gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs supporting weight gain, hyperglycemia, and diabetes became widely known. *See* Part II.B.4, *infra*.

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmalogical Drug Products requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 119 (E.D.N.Y. 2008). There is disagreement about whether the information given by Lilly to the FDA was complete and accurate.

As of November 2001, the Zyprexa label was revised to include, under the heading "ADVERSE REACTIONS," information alerting healthcare providers and consumers to the existence of cases of observed pancreatitis in patients taking Zyprexa:

> Postintroduction Reports—Adverse events reported since market introduction which were temporally (but not necessarily causally) related to Zyprexa therapy include the following: . . . *pancreatitis* . . . .

Ortenzio v. Eli Lilly & Co., Nos. 04-MD-1596, 07-CV-987, 2009 WL 1514628, at *5 (E.D.N.Y. June 1, 2009). The information regarding pancreatitis remains in the Adverse Reactions section of the Zyprexa label. Other second generation antipsychotics, such as Seroquel, carry similar risks of pancreatitis. *Id.*

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

> **WARNINGS**
> **Hyperglycemia and Diabetes Mellitus**
> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. . . .
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical

> antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. . . .

Letter from Russell Katz, M.D., Dep't of Health & Human Servs., to Gregory T. Brophy, Ph.D., Eli Lilly & Co., Sept. 11, 2003, at 1-2. The label did not mention weight gain or diabetes in the "warning to patients" section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. *See* Zyprexa Package Insert (Sept. 16, 2003). At the FDA's request, on March 1, 2004, it sent a "Dear Doctor" letter to physicians in the United States informing them of the 2003 label change. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 134-36.

2. *Consensus Statement of American Diabetes Association and Other Learned Groups*

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the "ADA consensus conference") on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes, FDA representatives, and atypical antipsychotic drug manufacturers. The panel reviewed the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the drugs

for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

> There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . .
>
> ***
>
> Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.
>
> ***
>
> Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.
>
> ***
>
> [T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice.
>
> Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

***

> These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to differ depending on the [atypical antipsychotic] used. Clozapine [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents.
>
> The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

American Diabetes Association, et al., Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, 27 Diabetes Care 596, 596-97 (Feb. 2004)

3. *FDA March 2007 Letter*

On March 27, 2007, the FDA raised new concerns about the adequacy of Zyprexa's warning label in a letter to Lilly:

> [W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . .
>
> Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. at 141 (quoting Letter from Thomas Laughren, FDA, to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007).

4. *Pancreatitis-Based Zyprexa Claims*

The potential causal link between Zyprexa and pancreatitis has been the subject of litigation activity since at least 2003:

> On February 27, 2003, Hersh & Hersh, a San Francisco, California, law firm, issued a press release announcing that it had filed "several" lawsuits on behalf of plaintiffs pursuing product liability claims related to Zyprexa. Press Release, Hersh & Hersh, *Hersh & Hersh Targets Eli Lilly's Most Profitable Anti-Psychotic Drug* (Feb. 27, 2003) (Business Newswire) . . . . According to the press release, the firm intended to file "numerous other complaints" and planned "to prove that as a result of taking Zyprexa, . . . their clients [had] sustained life-threatening or fatal injuries, including diabetes mellitus, hyperglycemia and pancreatitis."

In re Eli Lilly & Co. Sec. Litig., 549 F. Supp. 2d 496, 519-20 (E.D.N.Y. 2008). Beginning in 2003, numerous lawsuits were filed alleging pancreatitis caused by Zyprexa. *See, e.g.*, Compl. ¶ 6, *Souther v. Eli Lilly & Co.*, No. 06-CV-1729 (E.D.N.Y. filed Apr. 12, 2006).

Television advertisements have been aired by plaintiffs' law firms seeking potential plaintiffs who developed pancreatitis after taking Zyprexa. *See* Aff. of Adam B. Michaels in Further Supp. of Def.'s Mot. for Summ. J., Mar. 8, 2010, Ex. Z (still images and transcripts of Zyprexa-related law firm advertisements). Such an advertisement specifically referencing pancreatitis aired in August 2004, and similar advertisements aired from 2005 through 2007. *Id.* The Miller Firm, which represents Dixon in the instant case, aired an advertisement in April 2007 seeking Zyprexa-related claims of pancreatitis, among other conditions. *Id.*

5. *Findings on Medical Community's Knowledge of Zyprexa's Risks*

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent moments at which a patient, health care provider, institution, or the medical community at large arguably discovered that the cause of an alleged injury may have been the administration of

Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain might follow the administration of Zyprexa. The association between weight gain and heightened risk of diabetes was also broadly recognized by that time.

Formal events bringing this information to the medical profession include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on four motions for summary judgment in individual Zyprexa injury cases, this court found that, for purposes of these motions, the March 1, 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See, e.g., Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 278 (E.D.N.Y. 2007). In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that Souther's claim was barred by the statute of limitations:

> Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Gamine rather than Cusella, it became Dr. Ganime's duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.
>
> Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link

> between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.
>
> *Measured either against the date Cusella developed diabetes—August 1999—or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes—March 2004*—Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

Id. (emphases added; citations to record omitted).

The March 1, 2004 date represents the "latest possible date" prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. This court previously held that the November 2001 label revision represents the date when, for statutes of limitations purposes, physicians and their patients were deemed aware of the potential causal connection between Zyprexa and pancreatitis. *See Ortenzio v. Eli Lilly & Co.*, 2009 WL 1514628, at *9.

Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine – knew the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases including the instant one indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.,* Appendices A-D of *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.),* Nos. 04-MD-1596, 06-CV-1729, Docket Entries Nos. 88-1 to 88-4 (E.D.N.Y. June 11, 2007) (including relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. Plaintiff's Medical History and Treating Physicians' Decision to Prescribe Zyprexa

Plaintiff David Dixon has suffered from schizophrenia since the late 1970s, undergone many mental health hospitalizations, and taken many different psychiatric medications. Feb. 8, 2010 Aff. of Adam B. Michaels in Supp. of Def.'s Mot. for Summ. J. ("Michaels Aff."), Ex. C at DIXON_PROGRESS3_0431 (Mar. 23, 2005 Progress Note), Ex. D at DIXON_HUDSON_002 (Oct. 22, 1990 "Problem List"), -059-61 (Jan. 2, 1986 Discharge Summary), -063-64 (Apr. 14, 1985 Hospital Summary), Ex. E (Medication Profile Sorted by Issue Date). Dixon received Zyprexa from the Veteran Affairs Medical Center in Northport, New York ("VA Northport") from 1997 through June 2009. Michaels Aff., Ex. E.

In April 2004, Dixon was admitted to VA Northport suffering from necrotizing pancreatitis. Michaels Aff., Ex. F at DIXON_DISCHARGE_0044-45 (Sept. 20, 2004 Discharge Summary). Dixon advised the gastroenterologist consultant that he had previously suffered acute pancreatitis and undergone a pancreatic pseudocystectomy in 2000. Michaels Aff., Ex. G at DIXON_DISCHARGE_0254 (Apr. 13, 2004 Consult Request). The medical record of this hospitalization notes pancreatitis as part of Dixon's prior medical history. *Id.*

A year later, in March 2005, Dixon was admitted to VA Northport complaining of depression with auditory hallucinations. Michaels Aff., Ex. C at DIXON_PROGRESS3_0431. Dixon discussed his pancreatitis with admissions staff, saying he believed Zyprexa might be the cause of the disease and that he wanted to bring a lawsuit. But he said that he did not wish to discontinue Zyprexa. These comments are captured in the hospital's medical records:

> [Dixon] alludes to desire to sue regarding his pancreatitis citing that olanzapine [Zyprexa] may be the cause. However, he also states he does not wish to stop olanzapine. Literature reviewed. It is much more likely that [Dixon]'s continued alcohol abuse led to pancreatic pseudocyst. I would reconsider [prescription] for

> olanzapine as patient's MSE and self report of psychosis are not consistent. Malingering has been suspected of [Dixon] on previous occasions . . . .

Id. at DIXON_PROGRESS3_0439.

Despite his desire to remain on Zyprexa, Dixon's physicians at VA Northport discontinued the medicine in favour of Risperdal in March 2005 "due to patient's concerns it was contributing to his pancreas pathology." Michaels Aff., Ex. H at DIXON_DISCHARGE_0039 (Mar. 30, 2005 Discharge Summary). In an April 2005 consultation, Dixon noted that "Zyprexa helped my anxiety much better than [Risperdal]." Michaels Aff., Ex. I at DIXON_DISCHARGE_0189 (Apr. 7, 2005 Consult Request). By June 2005, Dixon was back on Zyprexa. Michaels Aff., Ex. E at DIXON_VAPHARM_0019.

Between January 26, 2006 and February 27, 2006, Dixon was hospitalized at VA Northport for a perihepatic abscess and pleural effusion. Michaels Aff., Ex. J at DD_01_006-11 (Feb. 27, 2006 Discharge Summary). On January 30, 2006 he was diagnosed with "type 2 diabetes, most likely due to chronic pancreatitis." Michaels Aff., Ex. K at DIXON_DISCHARGE_0172. The hospital records contain the following note:

> ASSESSMENT AND PLAN:
>
> 1) DIABETES
> – Pt with type 2 diabetes, most likely due to chronic pancreatitis. Past glucose values, HgbA1c, and his current symptoms suggest long-standing hyperglycemia.

On February 27, 2006, VA Northport discharged Dixon, furnishing him with instructions for managing his diabetes and a prescription to continue insulin for the next two weeks. Michaels Aff., Ex. L at DIXON_PROGRESS2_354-56 (Feb. 27, 2006 Progress Notes), Ex. M at

DIXON_PROGRESS2_0353 (Feb. 27, 2006 Progress Notes). His list of discharge medications included Zyprexa. Michaels Aff., Ex. M at DIXON_PROGRESS2_0353.

III. Law

A. Summary Judgment Standard

Summary judgment is appropriate only if "there is no genuine issue as to any material fact and if the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Mitchell v. Washingtonville Central School District*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 556 F.3d 137, 140 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See* Fed. R. Civ. P. 56(e). This evidence may not consist of "mere conclusory allegations, speculation or conjecture[.]" *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue.").

B. Choice of Law

A multidistrict litigation transferee court applies the choice of law and statute of limitations rules of the state in which the action was filed. *Menowitz v. Brown*, 991 F.2d 36, 40

(2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the instant action was originally commenced in New York, that state's choice of law principles apply.

Under New York law, the court applies the law of the state with the greatest interest in the litigation. *See, e.g., American BankNote Corp. v. Daniele*, 45 A.D.3d 338, 343 n.1 (N.Y. App. Div. 1st Dep't 2007) (citing *Padula v. Lilarn Props. Corp.*, 644 N.E.2d 1001, 1002 (N.Y. 1994)). Mr. Dixon ingested Zyprexa while living in New York, was prescribed Zyprexa in New York, and claims to have suffered injury as a result of Zyprexa in New York. As the only state with an interest in this litigation, New York's law applies to Mr. Dixon's claims.

C. Statute of Limitations

1. New York CPLR § 214-c(2)

The New York Civil Practice Law and Rules ("CPLR") create a limitations period for personal injury claims based upon exposure to pharmaceutical or other products of three years from discovery of the injury. CPLR section 214-c(2) provides:

> [T]he three year period within which an action to recover damages for personal injury or injury to property caused by the latent effects of exposure to any substance or combination of substances, in any form, upon or within the body or upon or within property must be commenced shall be computed *from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier.*

(Emphasis added.)

"Discovery of the injury" occurs, and the time for bringing action begins to run, when the injured party discovers the primary physical condition on which a claim is based: "[W]hen the Legislature used the phrase 'discovery of the injury' it meant discovery of the physical condition and not . . . the more complex concept of discovery of both the condition and the nonorganic

etiology of that condition." *Wetherill v. Eli Lilly and Co. (Matter of New York County DES Litig.)*, 678 N.E.2d 474, 478 (N.Y. 1997); *see also Major v. Astrazeneca, Inc.*, Nos. 5:01-CV-618, 5:00-CV-1736, 2006 WL 2640622, *56 (N.D.N.Y. Sept. 13, 2006) ("[F]or purposes of § 214-c(2), a cause of action for latent injury accrues when the plaintiff becomes aware of his symptoms, regardless of when he learns what caused those symptoms.").

"A diagnosis that one is suffering from a disease, even though unaware of its cause, is sufficient to start the running of the limitations period" for filing a claim based upon allegations of the latent effects of an exposure to toxic substances. *Hedlund v. County of Tompkins*, 235 A.D.2d 980, 982 (N.Y. App. Div. 3d Dep't 1997) (internal quotation marks and citation omitted). "All that is necessary to start the limitations period is that plaintiff be aware of the primary condition for which damages are sought." *Whitney v. Quaker Chemical Corp.*, 683 N.E.2d 768, 769 (N.Y. 1997).

2. New York CPLR § 214-c(4)

Section 214-c(4) of the CPLR creates a limited exception to section 214-c(2)'s three-year limitations period and discovery rule:

> Notwithstanding the provisions of subdivision[ ] two . . . of this section, where the discovery of the cause of the injury is alleged to have occurred less than five years after discovery of the injury or when with reasonable diligence such injury should have been discovered, whichever is earlier, an action may be commenced or a claim filed within one year of such discovery of the cause of the injury; provided, however, if any such action is commenced or claim filed after the period in which it would otherwise have been authorized pursuant to subdivision two . . . of this section *the plaintiff or claimant shall be required to allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been*

> *authorized* and that he has otherwise satisfied the requirements of subdivisions two and three of this section.

(Emphasis added.) Under section 214-c(4), a plaintiff whose claim does not fall within section 214-c(2)'s three-year limitations period may be granted an additional year from the date of discovery of the cause of injury to initiate an action. But the plaintiff must prove that sufficient scientific knowledge to ascertain the cause of injury was not available within the three-year limitations period. The burden of proving the unavailability of scientific information rests on the plaintiff. *See Pompa v. Burroughs Wellcome Co.*, 259 A.D.2d 18, 22 (N.Y. App. Div. 3d Dep't 1999) (citing cases).

The standards that govern application of section 214-c(4) were explained by the Appellate Division of the Third Department in *Pompa*:

> In evaluating when and whether the existing medical or scientific knowledge and information was sufficient to enable ascertaining the cause of plaintiff's symptoms, the focus is on the available knowledge of a causal relationship or connection between the substance at issue and the symptoms alleged by the plaintiff; *it does not require medical certainty or information sufficient to prevail at trial, but does entail showing that sufficient information and knowledge existed to enable the medical or scientific community to ascertain the probable causal relationship between the substance and plaintiff's injury.*

259 A.D.2d at 24 (emphasis added). *Pompa's* interpretation of section 214-c(4), including its "probable causal relationship" standard, was adopted by a federal district court applying New York Law in *Giordano v. Market America, Inc. (In re Ephedra Prods. Liab. Litig.)*, 598 F.Supp.2d 535, 536 (S.D.N.Y. 2009). The *Giordano* court understood *Pompa* as construing section 214-c(4)'s "sufficient to ascertain" language to mean "something akin to finding a probable connection," rather than "to find out or learn for a certainty." 598 F. Supp. 2d at 536.

The *Giordano* case involved a pharmaceutical personal injury claim concerning the drug ephedra, in which section 214-c(2)'s three-year limitations period expired in March 2002. The district court had held that there was a genuine issue of material fact as to whether, for purposes of section 214-c(4), sufficient scientific knowledge or information was available prior to March 2002 to permit plaintiff to ascertain the cause of his injury. *See Giordano*, 598 F. Supp. 2d at 537 (district court opinion). It was found that the state of scientific knowledge as late as 2005 "was insufficient to allow an expert witness to testify with any degree of medical or scientific certainty that ephedra caused the [alleged] injuries," but that "studies published as early as 1996 suggested a link between ephedra and" the injuries such that "some . . . scientific inquirers thought that the available information was reasonably suggestive (but hardly definitive) of a causal relationship." 598 F. Supp. 2d at 536-37 (internal quotation marks omitted). Further noted was that "most of the lawsuits asserting liability on the basis of [ephedra's] risks were not filed until after 2002, suggesting, at least, a lack of awareness of the risks by even the most interested members of the public prior to that time." 598 F. Supp. 2d at 537 n.1.

The district court expressed doubt about *Pompa's* interpretation of section 214-c(4), and suggested that the Court of Appeals for the Second Circuit consider certifying several issues to the New York Court of Appeals. *See* 598 F. Supp. 2d at 536-37 & n.1. On review, the appellate court accepted this suggestion and certified three questions regarding section 214-c(4) to the New York Court of Appeals, including the following:

> What standards should be applied to determine whether a genuine issue of material fact exists for resolution by a trier of fact as to whether "technical, scientific or medical knowledge and information sufficient to ascertain the cause of [the plaintiff's] injury" was "discovered, identified or determined" for N.Y. C.P.L.R. § 214-c(4) purposes?

Giordano v. Market America, Inc., 599 F.3d 87, 101 (2d Cir. 2010).

The New York court has not rendered its answers to the questions certified in *Giordano*. While the certified questions are pending, the law remains unchanged. The analysis prescribed in *Pompa*, and applied by the district court in *Giordano*, controls, including its "probable causal relationship" standard.

IV. Application of Law to Facts

1. New York CPLR § 214-c(2)

Dixon's claims were filed after the expiration of section 214-c(2)'s limitations period because they concern medical conditions known to Dixon more than three years before he filed suit on March 6, 2009. The medical records establish that before March 6, 2006 Dixon: (1) had been diagnosed with acute pancreatitis (2000); (2) had been hospitalized for necrotizing pancreatitis (April 2004); (3) had advised his doctors that he believed that his pancreatitis might have been caused by Zyprexa and he was considering a lawsuit (April 2004); (4) had been diagnosed with diabetes (January 2006); (5) had received insulin treatment for diabetes (February 2006); and (6) had received patient information and instructions for his diabetes (February 2006). Dixon does not dispute that his lawsuit was filed more than three years after his diagnoses of pancreatitis and diabetes. Pl.'s Opp. to Def.'s Mot. for Summ. J. at 9 ("Pl. Opp.").

2. New York CPLR § 214-c(4)

Section 214-c(4)'s exception to the three-year limitations period does not apply to Dixon's claims, because sufficient scientific knowledge to ascertain the cause of his injuries was available before the three-year limitations period on his claims expired.

To avail himself of section 214-c(4)'s exception to the limitations period, Dixon must show with respect to each of his claims that "technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration" of the three-year limitations period.

Dixon argues that his pancreatitis claims qualify for the extended limitations period under section 214-c(4). Pl. Opp. at 10. While he does not explicitly admit that his diabetes claims do not so qualify, he in effect concedes the point by failing to offer any section 214-c(4) arguments in support of the diabetes claims. *See id.* In any event, this court has held that March 1, 2004 is the latest possible date on which Zyprexa's obesity- and diabetes-related risks to patient health were known to the medical community and treating physicians. *See* Part II.B.5, *supra*. By this date, "technical, scientific or medical knowledge and information sufficient to ascertain" the causal role of Zyprexa in Dixon's diabetes "had [ ] been discovered, identified or determined" for purposes of section 214-c(4). Because this scientific knowledge predates Dixon's diabetes diagnosis in 2006, his diabetes-based claims do not qualify for section 214-c(4)'s exception.

With respect to the pancreatitis claims, the latest possible date on which Dixon can be said to have discovered his injury is April 2004, when he was hospitalized with necrotizing pancreatitis. *See* Part II.C, *supra*. Dixon must show that scientific knowledge linking Zyprexa to pancreatitis was not available until after April 2007, three years from his original diagnosis.

Scientific evidence potentially liking Zyprexa to pancreatitis existed at least as early as November 2001, when Zyprexa's label was revised to include pancreatitis among possible adverse reactions. *See* Part II.B.1, *supra*. The possibility of a Zyprexa-pancreatitis link was widely publicized in press releases and television advertisements by plaintiffs' law firms from

2003 through 2007, including an April 2007 advertisement aired by Dixon's counsel, the Miller Firm. *See* Part II.B.4, *supra*. Many pancreatitis-based Zyprexa claims were filed prior to 2007, demonstrating that "the most interested members of the public" were aware of the Zyprexa-pancreatitis connection. *See id.*; *Giordano*, 598 F. Supp. 2d at 537 n.1 (district court decision). Hospital records indicate that Dixon considered Zyprexa a possible cause of his pancreatitis in 2005. *See* Part II.C, *supra*. Statements by plaintiffs' experts in related Zyprexa cases suggest that the association between Zyprexa and pancreatitis was strongly supported in the medical literature as far back as 2000. *See* Reply Mem. of Law in Further Supp. of Def.'s Mot. for Summ. J. at 7-8 ("Def. Reply").

The record, including media reports and expert reports, *see, e.g.*, Def. Reply at 6-8, establishes that scientific evidence established a "probable causal relationship" between Zyprexa and pancreatitis before April 2007. *See Pompa*, 259 A.D.2d at 24. This scientific information was available to all relevant persons, including Dixon, his treating physicians, and his counsel. No further discovery or development by the parties would affect this conclusion.

Dixon argues that the statute of limitations should be equitably tolled, due to Lilly's fraudulent concealment of Zyprexa's causal connection to pancreatitis. Pl. Opp. at 16-18. The public availability of the relevant scientific information linking Zyprexa to pancreatitis means that any fraudulent concealment by Lilly did not prevent Dixon from discovering the nature of his claim within the limitations period. Tolling of the limitations period is not warranted.

V. Costs and Fees

Because plaintiff continues to press his claims even though, according to Lilly, "'it is patently clear that [the] claim[s] [have] absolutely no chance of success under the existing

precedents, and [. . .] no reasonable argument can be advanced to extend, modify or reverse the law as it stands,'" pursuant to Rule 11, Lilly seeks the costs and fees it has incurred in bringing this motion. Mem. of Law in Supp. of Def.'s Mot. for Summ. J. at 9 (alterations in original; quoting *In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 272 (E.D.N.Y. 2006)); *see also In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d at 272 ("In circumstances where the litigant causes unnecessary delay or needless increase to the cost of litigation, the typical sanction is the payment of the other side's reasonable attorney's fees which were incurred as a result of the improper filing.").

In view of plaintiff's mental problems and treatment as a veteran in a government facility, probably with reduced financial resources, the court declines to impose costs and fees.

VI. Conclusion

Dixon's claims are time-barred. Summary judgment is granted on the basis of the statute of limitations.

SO ORDERED.

Jack B. Weinstein
Senior United States District Judge

Date: May 19, 2010
Brooklyn, New York